VI. EFFECTS OF THE FINAL RULE ON INNOVATIVE ACTIVITY

Both direct effects, defined here as the incremental burden or costs incurred by a facility to comply with regulatory requirements (such as increased reporting costs and delayed product introductions), and indirect effects, defined here as a facility's response to the direct burden or costs incurred (such as shifts in the focus of research) must be considered in assessing the overall impacts of the rule on the biotechnology industry.* This chapter examines the indirect or "hidden" effects of the rule on innovation. The chapter is divided into three sections as follows:

- Section A presents a qualitative discussion of how the rule may impact innovation;
- Section B uses a simplified decision model to show how regulatory costs may affect the product development process and pace of innovation;
- Section C summarizes some important considerations in connection with assessing impacts on innovation.

A. The Final Rule's Effects on Innovation

The innovation question addressed in this chapter can be seen as a chain linking the rule to the ultimate effects imposed by the rule on the nation's welfare. The direct effects of the rule are to increase the cost and time to develop new products. These direct effects, however, could spawn indirect effects on the numbers of new products developed and the nature of those products. These indirect effects, in turn, can affect the economy as a whole and the welfare of society.

* While the focus of this chapter is on the potential for innovative impacts to occur resulting from incremental regulatory cost increases, regulatory costs for many products will be reduced relative to current policy, due to the exemption provisions of the final rule.

1. Direct Effects

The direct effects of the rule arise in connection with the time and expense associated with reporting to the federal government, plus the less tangible cost effects associated with possible delays in bringing new products to the market. Appendix F presents an assessment of the reporting costs that may be incurred on a per-product basis. These effects are expected to vary widely across different types of projects, with the highest incremental costs being for first-time products requiring extensive field testing. Costs associated with delayed products are potentially even more variable, with higher chances of a significant delay if a series of field tests is performed.

2. Potential Indirect Effects of the Final Rule on Innovation

Any indirect effects on innovation would most likely arise in connection with industry's product development strategies. First, the regulations could influence choices between using naturally-occurring microorganisms or engineering microorganisms to perform a task. Since the regulations would generally not apply to natural isolates, firms may tend to avoid engineering microorganisms if natural isolates provide a suitable alternative (Bourquin 1990, Mondello 1990, Shields 1990).

Second, if a firm chooses to use microorganisms subject to the rule, the regulations may affect how those microorganisms are developed and applied. For example, one industry source mentioned that a modular approach might be among the most effective approaches for bioremediation at a variety of sites. At each new site, the desired genes would be inserted into a microorganism isolated from the soil at that site. This would increase the chances of survival in the climate and special characteristics of each new location. However, since a separate submission could be required for each host, some firms may choose instead to develop a single product to be used at all sites.

Decisions regarding minor modifications in products could be influenced by the perception that potential delays in commercializing the product may exist. Since field testing is frequently seasonal, regulation could affect the scheduling of field tests or the number of field test locations.

While the indirect effects described above generally result in cost avoidance strategies or potential delays introduced into product development schedules, a firm may find the regulatory process to be a mechanism through which public resistance to a product due to misperceived risks may be reduced. In such a case, the costs incurred associated with the review process could accelerate a product's development schedule, thus mitigating the overall cost impact of regulation.

These potential effects may be acceptable in those cases in which they reduce risk significantly. However, they would be undesirable in cases where society may be deprived of useful low-risk products.

3. Links Between Direct and Indirect Effects

The nature and extent of innovation effects are difficult to predict and depend on the links between product development cost increases and changes in product development decisions.

The basic reason to expect indirect effects is that the development of commercial products in the biotechnology industry is guided by the profit motive. Since the rule would increase the costs of developing many products subject to regulation, firms may find it necessary to re-examine the expected return associated with a potential product.

The high degree of uncertainty surrounding both the potential for commercial success of a biotechnology product in a particular market area and the regulatory costs associated with its development make it impossible to estimate innovation impacts quantitatively. In addition, the extent to which

other factors may be involved in decision-making regarding product development is difficult to ascertain. Members of the regulated community may find weighing the financial risk of product development against potential returns to be difficult in many cases, and may need to ensure that other factors are adequately considered prior to making any decisions regarding product development. For example, the ability of a firm to raise capital or to market a potential product may override concerns regarding regulatory costs. The potential for regulatory review to reduce public resistance to products in the case of misperceived risks could also be a major consideration. Thus, the impact of regulatory requirements would be expected to be variable, and highly dependent upon product, market, and financial characteristics.

4. Links Between Indirect Effects on Innovation and Social Welfare

The value of new products to society is measured not only by their contribution to private profit, but also by their contribution to overall societal benefit. Unfortunately, information regarding the relationship between a product's profit making potential and the magnitude of its contribution to social welfare are not available; thus, no conclusions could be drawn with respect to the desirability or undesirability of innovation impacts from a perspective of social welfare.

It is the intent of the rule, however, that only those microorganisms which the Agency determines to pose the greatest uncertainties with regard to potential adverse effects be rigorously reviewed. This approach will ensure that negative impacts on social welfare are minimized by shifting the greatest regulatory burdens to products which have the highest probability of resulting in excessive social costs.

B. Links Between Regulatory Burdens And Innovative Activities

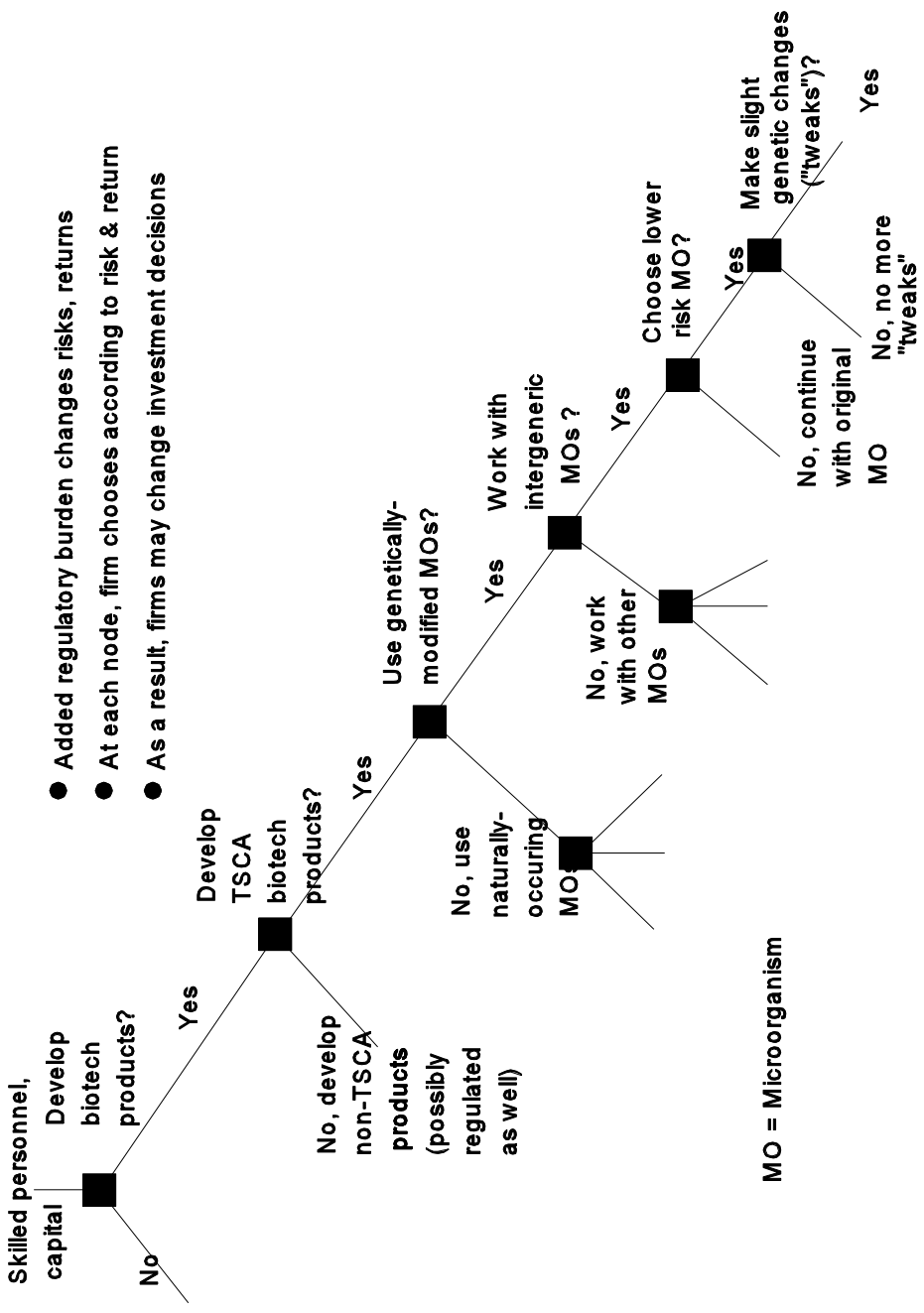
In this section, a simplified decision model is presented to illustrate how responses to the rule might be formulated by the regulated community. Figure VI-1 shows schematically the wide range of possibilities potentially open to a biotechnology firm, and the choices the firm might have to make in planning whether and how to develop a biotechnology product.

The firm can be pictured as having a certain amount of capital, a number of trained employees, and knowledge about the industry and potential markets. How it decides to proceed can be illustrated by its choice of one particular path through the diagram from top to bottom. At each node, or branch point, the firm must make a decision until it reaches one of the endpoints shown in the diagram.

Each of these branches will have certain advantages and disadvantages associated with it. In many cases, deciding not to develop any new products will have the least potential uncertainty and risk. On the other hand, the returns from this course could be relatively low, and there will be no chance to build for the future. Branches involving the use of new techniques to create products offer very different risks and payoffs, with higher potential gains in exchange for uncertainty and high costs.

The two decisions facing the firm -- whether to develop new products, and what types of microorganisms to use -- might in most cases be made through an informal decision process. Still, the decision process should implicitly consider or reflect some critical underlying factors. The most important factors will involve projections of the costs of proceeding down each path, the expected returns or benefits at the end of each path, the timing of the flows of costs and benefits, and the degree of predictability or riskiness of the flows along each path.

Figure VI-1
HYPOTHETICAL NEW PRODUCT DECISION TREE



Different firms might make different choices faced with the same situation. Hence, generalizations on firm behavior should be avoided since this is case-dependent. Sometimes, a company has no real choice of microorganism or area without a major reshuffling of resources. Often, however, a company is involved in both TSCA biotechnology and other market areas, and could shift resources relatively easily from one area to the other. Many companies engaged in TSCA biotechnology activities also are involved in activities not affected by the rule such as non-microbial chemicals, oil, food, and waste treatment, or medical and crop biotechnology. Hence, the main option for a firm wary of TSCA biotechnology regulations would seldom be less innovation as a whole, but rather other avenues of research not affected by the rule. In some cases (e.g. medical biotechnology), these other options would themselves involve high payoff, high risk, and regulation that may be much more extensive than TSCA biotechnology regulation.

C. Summary of Considerations

This chapter contains a number of points that policy makers should consider in assessing the rule and in choosing among options.

- Delays in new product introduction, a reduced number of product modifications during field testing, or product cancellation due to regulation all impose hidden costs on firms in the form of foregone profits. In some cases, these hidden costs may outweigh direct compliance costs.

- The cases in which impacts are most likely to stimulate reassessment of product development goals would be those involving long delays in commercialization induced by the regulatory review process, or involving a series of reporting steps that impose significant costs at each stage. Due to the flexibility in the rule, situations such as these can be avoided (and innovation impacts reduced).

- While regulatory costs are certainly one consideration in setting product development goals, other factors may be of equal or greater concern in many cases. Such concerns could include acquisition of capital and marketing ability.

- Tailoring the regulatory process to shift burdens toward those microorganisms associated with the greatest uncertainties regarding risk minimizes negative impacts, and may represent a net gain to society.

- Negative impacts on innovations are not necessarily harmful, because not all innovations may be valuable enough to outweigh the costs and risks they impose. The potential for harmful effects from biotechnology innovations provided impetus for the rule.

- In some cases where public resistance to products is based on misperceived risks, regulatory review may improve innovative potential.